

**EVALUATION OF THE JOINT CERTIFICATE OF NEED APPLICATION SUBMITTED ON
BEHALF OF EVERGREEN HOSPITAL MEDICAL CENTER AND OVERLAKE HOSPITAL
MEDICAL CENTER PROPOSING TO ESTABLISH OPEN HEART SURGERY AND PTCA
SERVICES WITHIN SPACE AT EVERGREEN HOSPITAL MEDICAL CENTER**

PROJECT DESCRIPTION

King County Public Hospital District #2 dba Evergreen Hospital Medical Center (EHMC) is a public hospital located at 12040 Northeast 128th Street in the city of Kirkland within King County. EHMC is currently a provider of Medicare and Medicaid services to the residents of Kirkland and surrounding areas. The hospital is licensed for 244 acute care beds¹ and holds a three-year accreditation from the Joint Commission on Accreditation of Healthcare Organizations and is designated as a level IV trauma hospital. EHMC also provides Medicare and Medicaid home health services to the residents of King County through its home health agency known as Evergreen Home Health. [sources: data provided by DOH Office of Health Care Survey, Office of Emergency Medical and Trauma Prevention, and CN historical files]

Overlake Hospital Medical Center (OHMC) is a not-for-profit hospital located at 1035 - 116th Avenue Northeast in the city of Bellevue, also within King County. OHMC is currently a provider of Medicare and Medicaid acute care services to the residents of east King County and surrounding areas. The hospital is licensed for 257² acute care beds, holds a three-year accreditation from the Joint Commission on Accreditation of Healthcare Organizations, and is designated as a level IV trauma hospital. Additionally, OHMC is one-third owner of a freestanding ambulatory surgery center (ASC) located on the hospital campus. The ASC, known as Overlake Surgery Center, has five operating rooms and two procedure rooms. [sources: data provided by DOH Office of Health Care Survey, Office of Emergency Medical and Trauma Prevention, and CN historical files]

Currently, OHMC provides open heart surgery (OHS) and PTCA services at its hospital; EHMC does not offer OHS or PTCA services. This joint application proposes to establish an OHS and PTCA program within space at EHMC. Before the services are established, however, OHMC and EHMC will establish, and be sole owners of, a new entity, tentatively known as Eastside Cardiac Care Alliance (ECCA). To establish OHS and PTCA services at EHMC, ECCA will enter into agreements with both hospitals, and ultimately be responsible for day-to-day operations of a single OHS and PTCA service operating at both hospitals. Joint management of the OHS and PTCA services will include: medical staffing, policies and procedures, quality assurance, professional education, and community outreach. [source: Application, pp7-8]

The applicants indicate throughout this application that this proposal should not be viewed as two OHS programs, rather, it is presented as one large, regional based OHS and PTCA program operating at two sites. For clarification purposes, while the two hospitals propose to share some staffing for the OHS programs, this project is clearly the establishment of OHS and PTCA services at EHMC. If, in the future, the relationship between the two hospitals were to dissolve, the result would still be two OHS programs at two separate sites, and the department would not expect either hospital would discontinue providing OHS or PTCA services. Therefore, this project is expected to meet the OHS standards as the establishment of a new OHS and PTCA service at EHMC.

¹ EHMC also has 17 skilled nursing beds banked under the full facility closure provisions of RCW 70.28.115(13)(b)

² On September 20, 2002, OHMC was issued CN #1248R approving the addition of 80 acute care beds to the hospital. At project completion, OHMC will be operating 337 acute care beds.

The proposed OHS and PTCA services will be offered within existing space at EHMC. OHS services will primarily be provided in operating room #7, with room #8 to be used as a back up. PTCA services will be provided in an existing cardiac catheterization laboratory. EHMC does not anticipate major construction to the hospital to accommodate the program. [source: October 30, 2002, supplemental responses, p8]

The funding to establish the OHS and PTCA services at EHMC will come solely from EHMC reserves. The estimated capital expenditure for this project is \$1,800,000, of which \$1,641,600 (or 91%) is related to moveable equipment. The remaining costs are associated with state taxes. [source: Application, p99]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new tertiary health service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(E).

APPLICATION CHRONOLOGY

The application chronology below is consistent with the Open Heart Surgery Concurrent Review Cycle outlined in WAC 246-310-132.

July 31, 2002	Letter of Intent Submitted
August 30, 2002	Application Submitted
August 31, 2002, through November 17, 2002	Department's Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses• 2nd screening activities and responses
November 18, 2002	Department Begins Review of the Application <ul style="list-style-type: none">• public comments accepted throughout review
January 16, 2003	Public Hearing Conducted
February 18, 2003	Rebuttal Documents Submitted to Department
April 14, 2003	Department's Anticipated Decision Date
May 27, 2003	Department's Actual Decision Date

AFFECTED PARTIES

As directed under WAC 246-310-110³, the department reviewed this project under the open heart surgery concurrent review cycle outlined in WAC 246-310-132. This application was reviewed concurrently with the application submitted by Good Samaritan Hospital. Throughout the review of this project, five entities sought and received affected person status under WAC 246-310-010:

- Good Samaritan Hospital located in the city of Puyallup within Pierce County;
- Harrison Memorial Hospital located in the city of Bremerton within Kitsap County;
- Providence Everett Medical Center located in the city of Everett within Snohomish County;
- Swedish Medical Center located in the city of Seattle within King County; and
- University of Washington Medical Center located in the city of Seattle within King County.

³ WAC 246-310-110 states (in summary) that the concurrent review process shall be used for all applications determined to be competing.

SOURCE INFORMATION REVIEWED

- Evergreen Hospital Medical Center and Overlake Hospital Medical Center's Joint Certificate of Need Application dated August 30, 2002 (received August 30, 2002)
- Evergreen Hospital Medical Center and Overlake Hospital Medical Center's joint supplemental information dated October 30, 2002, and November 30, 2002 (received October 31, 2002, and December 2, 2002)
- Comments provided throughout the review of the project
- Comments received at the January 16, 2003, public hearing
- Evergreen Hospital Medical Center and Overlake Hospital Medical Center's rebuttal comments dated February 14, 2003 (received February 18, 2003)
- Good Samaritan Hospital's rebuttal comments dated February 18, 2004 [sic] (received February 18, 2003)
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Office of Hospital and Patient Data Systems
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Office of Hospital and Patient Data Systems (April 17, 2003)
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (1999, 2000, and 2001 summaries)
- Population data obtained from the Office Financial Management based on year 2000 census published January 2002.
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Emergency and trauma designation data provided by the Department of Health's Office of Emergency Medical and Trauma Prevention
- Open Heart Surgery Standards and Need Forecasting Method under WAC 246-310-261
- Nonemergent interventional cardiology standards (PTCA) under WAC 246-310-262
- Data obtained from the Internet regarding health care worker shortages in Washington State
- Data obtained from the Internet regarding mileage and distance
- Certificate of Need Historical files

CRITERIA EVALUATION

To obtain Certificate of Need approval, EHMC and OHMC must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment); 246-310-261 (open heart surgery standards and methodology); and WAC 246-310-262 (nonemergent interventional cardiology standard).⁴

CONCLUSION

For the reasons stated in this evaluation, the joint application submitted on behalf of Evergreen Hospital Medical Center and Overlake Hospital Medical Center proposing to establish an open heart surgery and PTCA program within space at Evergreen Hospital Medical is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

⁴ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-240 (2) and (3).

A. Open Heart Surgery Standards and Need Forecasting Method (WAC 246-310-261)

Based on the source information reviewed, the department determines that the applicants have not met the standards and methodology criteria in WAC 246-310-261.

OHS and PTCA services are considered tertiary services as defined in WAC 246-310-010, which states (in summary) that tertiary services mean a specialized service meeting complicated medical needs of people. Tertiary services require sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care. For OHS and PTCA services, the department uses the established methodology and standards within WAC 246-310-261 to assist in its evaluation of need for the services. The following methodology calculations provided in this evaluation are for HSA #1 only. The complete methodology for Washington State is included in Appendix A attached to this evaluation.

Methodology

As a component of the need analysis, WAC 246-310-261 outlines a seven-step methodology for forecasting OHS need within a health service area (HSA).⁵ HSAs are identified in WAC 246-310-261, and are used for forecasting OHS needs. The methodology projects the number of surgeries by using the most recent three-year volumes reported for Washington State hospitals. OHS volumes are limited to Diagnosis Related Groupings (DRG) 104 through 109, inclusive. To obtain the number of OHS performed in an HSA, the department relies on historical Comprehensive Hospital Abstract Reporting System (CHARS) data provided by the Department of Health's Office of Hospital and Patient Data Systems (OHPDS).

EHMC is located in HSA #1, which includes the following ten counties: Clallam, Island, Jefferson, King, Kitsap, Pierce, San Juan, Skagit, Snohomish, and Whatcom. Step #1 of the methodology is a computation of the HSA's current capacity and three-year average percentage of out-of-state use of the area hospitals. Current capacity is defined as the sum of the highest reported annual volume for each hospital within a planning area during the most recent available three years data. This evaluation relies on 1999-2001 CHARS data.⁶ Data was used from the following 12 hospitals currently providing OHS and PTCA services within HSA #1.

King County	Children's Hospital & Medical Center Northwest Hospital Overlake Hospital Medical Center Swedish Medical Center-Providence Campus ⁷ Swedish Medical Center University of Washington Medical Center Virginia Mason Hospital
Pierce County	Mary Bridge Children's Hospital St. Joseph Medical Center Tacoma General Hospital
Snohomish County	Providence General Medical Center
Whatcom County	PeaceHealth dba St. Joseph Hospital

⁵ HSA's are established by geographic regions appropriate for effective health planning that include a broad range of health services.

⁶ Year 2002 CHARS data is not available as of the writing of this evaluation.

⁷ Formerly Providence Medical Center-Seattle

In September 2001, Harrison Memorial Hospital located in Kitsap County received Certificate of Need approval to provide adult OHS and PTCA services. As of the writing of this evaluation, the approved services are not yet operational, therefore, the CHARS data provided for years 1999-2001 does not include procedures performed at that facility.

Additionally, EHMC proposes to serve patients 15 years of age and older. Therefore, data from Children's Hospital and Medical Center and Mary Bridge Children's Hospital is included in the utilization and projections, however, their data is limited to those surgeries performed on patients 15 years of age and older.

Table I below identifies the age specific number of OHS provided within HSA #1.

Table I
Open Heart Surgery Volumes for HSA #1 Hospitals
Highest of 1999-2001 Volumes

	Age 15-44	Age 45-64	Age 65-74	Age 75+	TOTALS
Total number of discharges	314	2,094	1,506	1,294	5,208
Subtraction of HSA #1 three-year average number of out-of-state discharges = 3.35%	11	70	50	43	174
Total number of in-state discharges	303	2,024	1,456	1,251	5,034

As demonstrated in Table I above, the adjusted three-year high volume for HSA #1 hospitals is 5,034. To calculate steps two through seven in the methodology, the department combines like age specific volumes for years 1999-2001 for a three-year total volume for HSA #1. These totals are used to achieve three-year averages where necessary and to project OHS surgeries for year 2006.

Step #2 of the methodology requires a patient origin adjustment of the volumes data to determine HSA market shares and a computation of the planning area's age specific use rates. These results are shown in Tables II and III below.

Table II
HSA #1 Use Rates Per 100,000 Based on 1999-2001 Volumes

Use Rate	Age 15-44	Age 45-64	Age 65-74	Age 75 +
3-Year Averages	15.52	214.98	655.53	589.44

Table III
HSA #1 Percentage of Market Share Based on 1999 - 2001 Volumes

	Age 15-44	Age 45-64	Age 65-74	Age 75 +
HSA #1(own market share)	99.75%	99.56%	99.50%	99.74%
HSA #2	31.73%	17.16%	16.65%	18.21%
HSA #3	26.90%	14.32%	15.23%	12.50%
HSA #4	2.03%	0.61%	0.44%	0.36%

To project the number of OHS anticipated in HSA #1 by year 2006 as directed in Step #3, the three-year average use rates (from Table II) are applied to the projected year 2006 population, which is summarized in Table IV below.

Table IV
Projected Open Heart Surgeries for Year 2006 Residents of HSA #1

	Age 15-44	Age 45-64	Age 65-74	Age 75+
Projected Year 2006 Population	1,703,446	1,041,495	225,764	210,755
Average Use Rate (from Table II)	15.52	214.98	655.53	589.44
Projected # of Surgeries per 100,000 Population	264	2,239	1,480	1,242

Step #4 in the need methodology is the use of market share to project the number of Washington State residents expected to have OHS in a hospital within HSA #1 in year 2006. This calculation is derived by multiplying the projected number of surgeries shown in each corresponding HSA's Table IV within the methodology by the market share percentages shown in Table III. Table V below is a summary of this calculation.

Table V
HSA #1 Projected Number of Surgeries for Year 2006

	Age 15-44	Age 45-64	Age 65-74	Age 75 +	TOTAL
HSA #1 (own market share)	264	2,229	1,473	1,239	5,205
HSA #2	11	60	50	41	162
HSA #3	13	50	43	30	136
HSA #4	2	2	1	1	6
TOTALS	290	2,342	1,566	1,311	5,509

Note that whole numbers may not add due to rounding

As shown in Table V above, for year 2006, the projected number of patients to be served by the 13 hospitals within HSA #1 that have an established OHS program, or--in the case of Harrison memorial Hospital, will have an established OHS program-- is 5,509.

Step #5 adjusts this number to include projected out-of-state activity. The 1999-2001 methodology shows a three-year average of 3.35% of HSA #1 surgeries were out-of-state residents (Table I). Applying this number for year 2006 surgery projections yields 191 out-of-state residents being projected to use OHS services in HSA #1. This results in a projected total number of surgeries in year 2006 for HSA #1, including out-of-state residents, to be 5,700.⁸

Step #6 in the methodology requires subtracting the current capacity (highest reported OHS annual volume) from the projected need. Using annual volume figures for years 1999-2001, current capacity from Table I is 5,208. Therefore, the number of additional surgeries projected in HSA #1, or the projected net need, for year 2006 is 492.⁹

Step #7 states (in summary) that if the projected net need is less than the current minimum volume of 250 procedures as required by WAC 246-310-261(3)(a), then no new programs shall be assumed to be needed in the planning area. Given that the projected net is 492, step #7 does not apply.

The mathematical calculation portion of the methodology found in WAC 246-310-261 demonstrates that the addition of at least one OHS program in HSA #1 is reasonable. The department must now determine whether the EHMC project meets the seven standards outlined in the methodology.

⁸ 5,509 plus 191.

⁹ 5,700 minus 5,208.

Standards

Standard #a:

A minimum of 250 open heart surgery procedures per year shall be performed at institutions with an open heart surgery program.

EHMC estimates that 150 OHS would be performed in year one, 210 in year two, and 260 by the end of the third year of operation, which is 2007. [source: Application, p18] These estimates are based on written, verifiable documentation that EHMC physicians have referred 278 OHS cases to area hospitals in the twelve months from March 2000 through February 2001. [source: EHMC October 30, 2002, supplemental responses, Attachment 4, and EHMC rebuttal documents, p7] As shown in step #6 of the methodology, the department projects approximately 492 additional OHS will be performed in HSA #1 by year 2006. Therefore, solely based on EHMC's historical referrals, the total number of surgeries projected to be performed by the end of year three may be at least 250. This standard is met.

Standard #b:

Hospitals applying for a Certificate of Need shall demonstrate that they can meet one hundred ten percent of the minimum volume standard. To do so, the applicant hospital must provide written documentation, which is verifiable, of open heart surgeries performed on patients referred by active medical staff of the hospital. The volume of surgeries counted must be appropriate for the proposed program (i.e., pediatric and recognized complicated cases would be excluded).

The department recognizes that generally the patient's attending cardiologist is the primary influence that determines where the patient will receive OHS services and that hospitals contract with selected cardiology groups. Even though an applying hospital can demonstrate a history of referring 250 or more surgeries to institutions with OHS capabilities, it is unlikely that an applying hospital would re-capture 100% (all 250) of those referrals. Therefore, to assure that the applying facility would perform a minimum of 250 OHS by the end of the third year of operation, the department requires institutions applying for new heart surgery programs to demonstrate it has referred a minimum of 275 or 110% of the 250 minimum number of surgeries.

As stated in standard #a above, EHMC provided referral documentation for a total of 278 patients for the twelve months from February 2000 through March 2001. [source: EHMC October 30, 2002, supplemental responses, Attachment 4, and EHMC rebuttal documents, p7] The population of HSA #1 for residents 15 years and older is expected to reach approximately 3,181,460 by year 2006. [source: OFM projected population data] This is a 7.5% increase over the estimated year 2000 population for HSA #1. On the basis of the calculations of the projected percentage of population increase for HSA #1, the department expects this proposal would meet this standard by the end of the third year of operation. This is consistent with WAC 246-310-261(3)(g) which allows hospitals three years from the date the program is initiated to meet this standard. Further, the department concluded that all 278 patients would be considered consistent with standard #a. This standard has been met.

Standard #c:

No new program shall be established which will reduce an existing program below the minimum volume standard.

According to CHARS data, the following numbers of OHS were performed in HSA #1 hospitals in 2001. [source: Year 2001 CHARS data less out of state activity]

Table VI
Year 2001 Number of Open Heart Surgeries
Performed in HSA #1 Hospitals

Facility Name/County Location	# of Surgeries
Children's Hospital & Medical Center, King County (15+ yrs)	14
Mary Bridge Children's Hospital, Pierce County (15+ yrs)	5
Northwest Hospital, King County	151
Overlake Hospital Medical Center, King County	367
PeaceHealth dba St. Joseph Hospital, Whatcom County	285
Providence General Medical Center, Snohomish County	595
Swedish Medical Center-Providence Campus	381
St. Joseph Medical Center, Pierce County	679
Swedish Medical Center, King County	751
Tacoma General Hospital, Pierce County	389
University of Washington Medical Center, King County	398
Virginia Mason Hospital, King County	629

Harrison Memorial Hospital is not included in Table VI above because it received approval for adult OHS in September 2001 and, as of the writing of this evaluation, the program is not yet operational. As shown in Table VI, both Children's Hospital and Medical Center and Mary Bridge Children's Hospital are considerably below the minimum volume standard of 250 OHS. The department notes, however, that these two providers primarily serve patients under the age of 15. Therefore, the department expects both of these hospitals to have a relatively small number of OHS procedures for patients in the 15 years and older age group.

Verifiable documentation provided by EHMC shows that the 278 patients were referred to seven of the twelve HSA #1 area hospitals for OHS. Table VII below identifies the hospital where EHMC physicians referred its 278 patients. [source: EHMC October 30, 2002, supplemental responses, Attachment 4]

Table VII
February 2000-March 2001 Evergreen Hospital Open Heart Surgery Referrals

Facility Name/County Location	# of Referrals	% of 284 Total
Veterans Hospital, King County	2	0.7%
Providence Everett Medical Center, Snohomish County	4	1.4%
Northwest Hospital, King County	8	2.9%
University of Washington Medical Center, King County	10	3.6%
Virginia Mason Medical Center, King County	28	10.1%
Swedish Medical Center, King County	103	37.1%
Overlake Hospital Medical Center, King County	123	44.2%
Total	278	100.0%

As shown in Table VII above, 226 (or 81%) of the total number of EHMC patients were referred to two King County hospitals with OHS capabilities--Swedish Medical Center (103) and Overlake Hospital Medical Center (123). If EHMC were to re-capture 100%, or all 226, of these patients, the impact to these two hospitals would be:

- Swedish Medical Center would serve 648 patients (751 minus 103); and
- Overlake Hospital Medical Center would serve 244 patients (367 minus 123).

Using the simple mathematical calculation above, approval of EHMC's project would reduce Overlake Hospital Medical Center below the 250 standard.

To demonstrate the potential impact of its proposed program, EHMC provided the following information and presented the table below. [source: Application, pp41-42]

“...the establishment of an open-heart surgery program at Evergreen will not result in any provider falling below the minimum volume standard of 250 cases annually. Table 6 [below] details, for 2001, the total volumes for HSA #1 hospitals and the number and percentage of these volumes that were generated by Eastside residents.”

TABLE 6 PROVIDED BY EHMC [source: Application, p41]				
Hospital Name	Location	Total Discharges	Greater Eastside Discharges	Greater Eastside Resident Percent of Discharges
Swedish Medical Center	Seattle	1,164	247	21.2%
St. Joseph Medical Center	Tacoma	687	5	0.7%
Virginia Mason Hospital	Seattle	674	150	22.2%
Providence Everett Medical Center	Everett	602	109	18.1%
U of W Medical Center	Seattle	431	55	12.8%
Tacoma General Hospital	Tacoma	393	3	0.8%
Overlake Hospital Medical Center	Bellevue	376	330	87.7%
St. Joseph hospital	Bellingham	293	2	0.7%
Northwest Hospital	Seattle	154	50	32.5%
Children's Hospital	Seattle	15	5	N/A
Mary Bridge Children's Hospital	Tacoma	5	0	N/A
Total		4,794	956	19.95%

The following statements are footnotes provided by EHMC associated with the table above:

- *Swedish Medical Center-throughout this report, Swedish-Providence and Swedish First Hill volumes are combined and included as Swedish Medical Center; and*
- *According to CHARS, there were a total of 964 adult discharges of greater Eastside residents within DRGs 104-109, of these 964, 956 occurred in HSA #1 hospitals.*

Information provided in the table does not appear to substantiate the applicants' assertions restated above the table. In fact, the relationship between the assertions and the table is unclear. Further, the statements and the table are not relevant to EHMC's referral patterns for OHS or the impact of the proposed services on existing OHS providers in the state. The department concludes that the above information does not demonstrate compliance with this standard.

In response to written comments provided at the public hearing, EHMC provided the following information and table related to this standard. [source: EHMC February 14, 2003, rebuttal documents, p7-8]

“Swedish and Providence-Everett have confused the requirements around documentation of cases and minimum volumes. WAC 246-[310]-261(3)(b) requires that an applicant demonstrate that physicians on its active medical staff have referred at least 275 cases in a recent 12 month period for open heart surgery. To conform to this standard, Evergreen and Overlake placed on the record verifiable data for the period of March 2000 through February 2001. This very laborious effort of matching cases required us to: 1) verify the referring cardiologists' records; 2) verify the surgeons' records; 3) where possible, contact the hospital at which the surgery was performed; and/or 4) match the data against the CHARS database.

This process was initiated by Evergreen and Overlake in January of 2002, and was not completed until late summer of 2002. The verified data demonstrates that Evergreen's active medical staff referred the following number of cases to open heart surgery at the following institutions...[chart included depicting the first two columns shown in the department's Table VII above]. The table below uses 2001 CHARS data to document that the potential Evergreen loss will not cause any existing provider to fall below the minimum volume standard."

TABLE 2 PROVIDED BY EPMC			
<i>[source: February 14, 2003, Rebuttal Documents, p8]</i>			
Existing Provider	2001 Adult Open Heart Cases	Less EP Verified Cases	Net Remaining Cases
Swedish/Providence Seattle	1,164	103	1,061
Overlake Hospital Medical Center	376	123	253
Veterans Administration	N/A	2	N/A
Northwest Hospital	154	8	146
Providence Everett Medical Center	602	4	598
University of Washington	431	10	421
Virginia Mason	674	28	646

The following statements are footnotes provided by EPMC associated with the statements and table above:

- *Northwest is already operating below the minimum threshold. Therefore, the potential loss of 8 additional cases will not be the cause of the hospital operating below the standard.*
- *While our active medical staff referred 123 cases to Overlake, the "loss" of cases to Overlake is expected to be in the range of 80-100 in the first year, because the more complex, less stable cases will continue to be performed at Overlake.*

After reviewing the information provided by EPMC to demonstrate compliance with this standard, the department concludes the following:

- The year 2001 adult OHS shown in the table above includes out of state cases. Occasionally a patient is traveling through Washington State when the need for cardiac services arises. The number of out of state cases is unpredictable and should not be included when determining the impact of a new provider. Year 2001 CHARS data shows that OHMC provided a total of 376 OHS on patients 15 years of age and older. Of those 376, 9 were out of state patients, resulting in 367 OHS on Washington State residents. Once EPMC's 123 patients are subtracted from OHMC's total of 367 in-state patients, OHMC's volume is reduced to 244 patients, which is below the 250 standard and verified by the department's calculations directly below Table VII above.
- Approval of this joint program at EPMC will also impact Northwest Hospital's volumes. EPMC indicates that since Northwest Hospital is currently operating below the minimum volume of 250 OHS, loss of another 8 cases will not be the cause of the hospital to fall below the 250 volume. However, the exact wording of this standard is: *"No new program shall be established which will reduce an existing program below the minimum volume standard."* [emphasis added] Therefore, approval of a new program does not have to be the cause of an existing program to fall below the minimum volume of 250 as EPMC claims. Further, approval of a new OHS program should not contribute to a facility's inability to meet this standard. While EPMC may not refer a large number of OHS to Northwest Hospital, the

department has no way of determining how many of the 492 OHS projected to be provided in HSA #1 (results of the mathematical calculation portion of the methodology) would be served at Northwest Hospital. Approval of an OHS program at EHMC will contribute, at some level, to Northwest Hospital's inability to reach the minimum volume of 250, which is contrary to this standard.

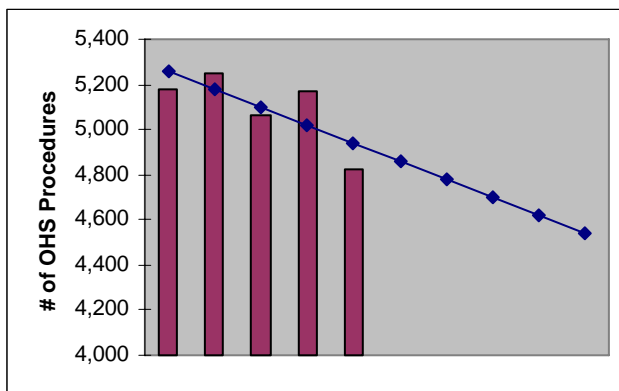
To assist in its evaluation of the impact on existing providers, the department reviewed the historical number of OHS for Overlake Hospital, Northwest Hospital, HSA #1 as a whole, and Washington State for years 1997 through 2001. A summary of that review is shown in Table VIII below.

Table VIII
Volumes for Years 1997-2001

YEAR	OVERLAKE HOSPITAL	NORTHWEST HOSPITAL	HSA #1	STATE TOTAL
1997	351	2	5,176	7,366
1998	320	136	5,251	7,277
1999	339	170	5,061	7,199
2000	330	170	5,171	7,362
2001	376	151	4,820	7,174

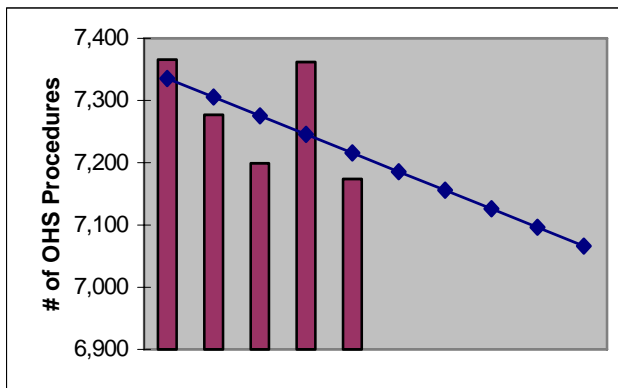
Northwest Hospital's OHS program began in year 1998, therefore, the two procedures performed in 1997 would have been emergent procedures. The program at Northwest Hospital has not yet reached 250 minimum procedures since the program's inception in 1998. In its CN application, Northwest Hospital projected to provide 289 OHS by the end of its third year of operation--year 2000--instead Northwest Hospital provided slightly over ½ of its projected number of procedures. Further, the number of procedures at Northwest Hospital has decreased from year 2000 to 2001. [source: CN historical files] Overlake Hospital's OHS program has remained relatively consistent, however, it has experienced a slight decrease in procedures in 1998 and 2000. For both HSA #1 and Washington State as a whole, the OHS volumes have decreased more often than increased from year to year. Additionally, overall from year 1997 to year 2001, the volumes have substantially decreased for the state and for HSA #1--a 2.6% overall decrease for the state and 6.9% overall decrease for the HSA.

Using the five years historical data for OHS, the department applied a regression analysis to determine the projected number of OHS to be performed for HSA #1 and the state. The results of the projections are shown below.



HSA #1 Trends 2002-2006

If the current OHS trend continues, as the chart on the left illustrates, the number of OHS projected for HSA #1 is expected to substantially decrease.



Washington State Trends 2002-2006

Again, as with the HSA #1 trend, if the current OHS trend continues for the state, as the chart on the left illustrates, the number of OHS projected for Washington State is expected to substantially decrease.

The trends illustrated in the charts above demonstrate a projected decline of OHS in the state and HSA #1 based on five years OHS historical data. Data reviewed by the department suggests that the demand for cardiac services will continue to grow across the nation as the population ages, however, the demand for cardiac services is expected to shift from OHS to other interventional procedures. Many factors have led to this decline, including the increase in technological interventions and cardiac medications. Regardless of the cause, the expected and projected effect is decreased OHS volumes--in HSA #1, Washington State, and nationally.

EHMC also suggests that it would not recapture all 123 patients from OHMC in the first year of operation--probably only 80 to 100 would be recaptured--because the complex and less stable patients will continue to be referred to OHMC for services. EHMC suggests that the lesser number of referrals in year one will not reduce OHMC below the 250 standard, and therefore, should be considered when evaluating this standard. The department recognizes that the determination of how many referrals will be recaptured is not an exact mathematical calculation. However, as the department understands from the information provided in the application, even if EHMC does not recapture a substantial portion of its referrals from OHMC in year one, it undoubtedly intends to recapture those referrals by the end of year two or three when the new program is accepting the more complex cases.

In summary, the department concludes that the applicants' fail to demonstrate compliance with this standard, and approval of this project would negatively affect OHMC by decreasing its volume of OHS procedures below the standard of 250 OHS per year. Further, approval of this project would negatively affect Northwest Hospital by further reducing its number of OHS procedures below the 250 standard and contributing to Northwest Hospital's inability to reach its 250 minimum volume standards. Finally, given that OHS volumes are on the decrease for OHMC, HSA #1, and the state as a whole, approval of this project would simply not be prudent at this time. Therefore, this standard is not met.

Standard #d:

Open heart surgery programs shall have at least two board-certified cardiac surgeons, one of whom shall be available for emergency surgery twenty-four hours a day. The practice of these surgeons shall be concentrated in a single institution and arranged so that each surgeon performs a minimum of 125 open heart surgery procedures per year at that institution.

The intent of this standard is to ensure that the cardiac patient is treated by cardiac physicians and support staff that has attained the high success rate only achieved by the physician and staff volume/quality relationship with the cardiac surgeries. To demonstrate compliance with this standard, EHMC provided the following statement:

“...The two existing board-certified surgeons based at Overlake Hospital, who have more than twenty years of experience, will also staff the Evergreen program. In addition, a third cardiac surgeon will be recruited prior to the opening of the service at Evergreen, and a fourth as volume requires. Each surgeon is expected to perform more than the minimum of 125 open heart surgeries per year by the third year of operation. The two existing surgeons are employees of Overlake Hospital, and will eventually become employees of the new entity. Likewise, the to-be-recruited third surgeon will also become an employee. As such, no contract exists, but the employee-employer relationship ensures 24/7 exclusive availability to the two Eastside hospitals. [source: Application, p43; and October 30, 2002, supplemental responses, p11]

As indicated above, as of the writing of this evaluation, there is no contract between EHMC and a cardiac entity for the cardiology services to be provided. Given that this cardiac project is still in the CN review phase, the two hospitals have not yet established the new entity to operate both cardiac services--ECCA (Eastside Cardiac Care Alliance). Therefore, the department is unable to review a draft agreement to determine compliance with this standard.

The applicants' provided an executed Memorandum of Understanding (MOU) that provides a very condensed summary of the intent of the joint application as it relates to both hospitals and outlines the anticipated roles and responsibilities of the medical director. The MOU does not identify any costs associated with the relationship. Under the MOU at least one of the cardiac surgeons will be a resident in the eastside on a permanent basis. [source: Application, Exhibit 2] After reviewing the information provided by the applicants in relation to this standard, the department concludes that without at least a draft agreement between ECCA and the two hospitals, it is unable to conclude that the intent of this standard is met.

Standard #e:

Institutions with open heart surgery programs shall have plans for facilitating emergency access to open heart surgery services at all times for the population they serve. These plans should, at minimum, include arrangements for addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.), and the maintenance of, or affiliation with, emergency transportation services (including contingency plans for poor weather and known traffic congestion problems).

As stated in the project description portion of this evaluation, OHS services at EHMC will primarily be provided in operating room #7, with room #8 to be used as a back up. If both rooms were in use and an emergent OHS patient was admitted, OHS could be performed in any of the remaining ORs as an emergent solution. In any event, EHMC will require an average of 45 minutes to prepare the OR and staff for OHS. PTCA services will be provided in an existing cardiac catheterization laboratory. [source: October 30, 2002, supplemental responses, p8]

EHMC will serve patients 15 years of age and older. Patients 14 years and younger will primarily be referred to Children's Hospital and Regional Medical Center in Seattle. [source: October 30, 2002, supplemental responses, p5]

Additionally, in response to this standard, the applicants provided the following statements:

“Ultimately, the two hospitals will operate one single open heart surgery program-on two distinct campuses. Protocols will dictate that all effort will be given to moving the surgical team to the patient; thereby minimizing patient transfers. Transfer will only be required in three instances: 1) the patient’s need is quaternary; 2) it has been determined that the surgical team can not be assembled on site within 60 minutes of request; or 3) patient/family or payer preference. [source: October 30, 2002, supplemental responses, p11]

To further comply with this standard, the applicants’ provided a sample, draft transfer agreement intended to be similar to the transfer agreement to be implemented prior to commencement of the program. [source: October 30, 2002, supplemental responses, Attachment 5] The draft agreement provided omitted key information used by the department to evaluate compliance with this standard, such as whether the agreement would be between ECCA, OHMC, or EHMC and a tertiary provider.

The department understands that EHMC intends to comply with this standard, however, after reviewing the sample transfer agreement, the department concludes that it is unable to evaluate this project’s conformance with this standard, and therefore cannot conclude that this standard is met.

Standard #f:

In the event two or more hospitals are competing to meet the same forecasted net need, the department shall consider the following factors within determining which proposal best meet forecasted need.

- (i) The most appropriate improvement in geographic access;*
- (ii) The most cost efficient service;*
- (iii) Minimizing impact on existing programs;*
- (iv) Providing the greatest breadth and depth of cardiovascular and support services; and*
- (v) Facilitating emergency access to care.*

Consistent with this standard, the department is evaluating this project under concurrent review with the project submitted by Good Samaritan Hospital in Puyallup. Therefore, this standard applies to this project.

Standard #g:

Hospitals granted a Certificate of Need have three years from the date the program is initiated to establish the program and meet these standards.

As stated in Standard #a, Step #6 of the methodology projects approximately 492 additional OHS will be performed in HSA #1 by year 2006. EHMC anticipates providing 260 surgeries by the end of its third year of operation, however, as stated in standard #c in this evaluation, EHMC would achieve this volume at the expense of--in the case of OHMC--reducing an existing program below the minimum volume and--in the case of Northwest Hospital--exacerbating the current low volume of an existing program. Further, given that OHS volumes are declining in the HSA and Washington State, the department is unable to conclude that EHMC’s projections are reasonable. This standard is not met.

Concerns raised in opposition to this project related to the OHS standards under WAC 246-310-261 were provided by the following three entities:

Everett Cardiac Surgical Group
Providence Everett Medical Center
Swedish Medical Center

The department has summarized the concerns from all three entities below.

Everett Cardiac Surgical Group

The application should be denied as it is not operationally viable.

[source: public comments provided at January 16, 2003, public hearing]

Providence Everett Medical Center

Opposition is based on the following grounds:

- The proposed venture is not operationally viable.

[source: public comments provided at January 16, 2003, public hearing]

Both Everett Cardiac Surgical Group and Providence Everett Medical Center state that the project is not operationally viable. Excerpts from those comments are provided below:

"We do not see how it will be possible for two full service programs to be able to sustain themselves from a manpower perspective by dividing up the volume in two campuses. We perform roughly the same number of surgeries now that the combined entity is anticipating, and our hospital finds it hard to fully staff our team and have an adequate call rotation for this team and associated physicians in only one location. A second location would divide these resources in half and quickly lead to burn out and turn over. There is already a shortage of skilled open-heart surgical team staff, perfusionists, cardiac anesthesiologists, and ICU staff. This proposal calls for two teams on call every night, including two surgeons out of a population of two, i.e. the physician is on emergency call every night compared to every other night at one institution alone as is now the case at Overlake. Even with the hiring of a third surgeon as the applicants submit, the rotation only improves to two nights on, off one. This is a sure formula for physician burn out. Even with this rotation ameliorated, the rest of the team needs to be large enough to share a reasonable call schedule yet the volumes don't warrant that size of a team. Therefore, the team will be forced to perform a lower volume of open heart cases than a smaller team in a single program would perform, reducing skill and experience."

[source: public comments provided at January 16, 2003, public hearing]

In response to the comments provided above, EHMC and OHMC provided the following responses.

"...first and foremost, it must be reiterated that the Evergreen/Overlake collaboration cannot be construed as two programs. Rather, this collaboration will create one large regional program (based at two sites to ensure access), but clearly functioning as one program. The surgeons, staffing, protocols, procedures, and administrative oversight will be the same at each site. In other words, regards of where a patient elects to have (or is emergently sent for) open-heart surgery on the Eastside, that patient's experience and care will be the same. Overlake's two existing surgeons practice exclusively at Overlake and cover that cardiac surgery program with a call schedule that ensures 24/7 availability. Adding a third surgeon (who will practice exclusively as well) in the early years of the dual program will ensure that both sites are covered 24/7, while

also ensure that each surgeon performs the number of cases necessary to maintain outcomes and staff proficiency....” [source: February 14, 2003, rebuttal documents, p4 and p9]

Department's Review

As indicated under Standard #d above, the two hospitals have not yet established the new entity to operate both cardiac services--ECCA, therefore, at this time, there is no contract between EHMC and a cardiac entity for the cardiology services to be provided. The department is unable to review a draft agreement to determine compliance with many of the standards under WAC 246-310-261, and specifically Standard #d. The applicants' provided a Memorandum of Understanding (MOU) that provides a very brief outline of the intent of the joint application as it relates to both hospitals and outlines the anticipated roles and responsibilities of the medical director. Under the MOU at least one of the cardiac surgeons will be a resident in the eastside on a permanent basis. [source: Application, Exhibit 2] As a result and as previously stated, the department concludes that without at least a draft agreement between ECCA and the two hospitals, it is unable to conclude that the intent of Standard #d is met.

Additionally, the department recognizes that it is the applicants' intent to establish one cardiac program to be operated at two sites--the existing site at OHMC and this proposed site at EHMC. However, as stated in the project description portion of this evaluation, the department considers this application as the establishment of OHS and PTCA services at EHMC. As such, the project must meet all relevant review criteria associated with its establishment. The staffing standard under WAC 246-310-261 requires the two proposed cardiac surgeons perform a minimum of 125 OHS to ensure compliance with standards outlined in WAC 246-310-261, for a total of 250. . Once the third cardiac surgeon is added at EHMC, this surgeon will also be required to perform 125 OHS at the EHMC. If the surgeons anticipate to be operating at both EHMC and OHMC, the department would expect the surgeons to provide a minimum of 125 OHS at both sites to maintain compliance with this standard. Although the existing program at OHMC is not under review at this time, OHMC is also expected to maintain continued compliance with the standards under WAC 246-310-261. Therefore, the department shares the same staffing concerns raised by both Everett Cardiac Surgical Group and Providence Everett Medical Center and cannot conclude that the applicants have adequately addressed the concerns.

Swedish Medical Center

- Open heart utilization is on the decline
- Low volumes adversely affect quality and outcomes
- Duplication of existing eastside capacity and services

[source: public comments provided at January 16, 2003, public hearing]

Swedish Medical Center provided extensive documentation and supporting documentation outlining the concerns above. In response to those concerns, the applicants' provided the following responses. Below is a summary of the applicants' response to the concerns and the department's review.

Open heart utilization is on the decline

“Swedish states that for the period 1995-2001, open heart surgery cases declined by 11% in the state of Washington. This statement is very misleading and inaccurate. Presented in Attachment 1, and summarized in Table I below, use rates have decreased in Washington State by 2% and volumes have actually increased by almost 7%--a direct

result of the growth and aging of the population.¹⁰ More importantly, the methodology the state has adopted into WAC captures and adjusts for changing use rates. Specifically the state methodology averages three years of historical use rates and then projects them into the future. If/when volumes during the most previous three-year period are declining, the projections of future need will reflect the downward trend. Because the average 1999-2001 experience was relatively flat, the latest estimates produced by the DOH in January of 2003 (which incorporates CHARS data for the years 1999-2001), depict the need for two additional open heart programs in HSA #1. This need is directly correlated to a growing and aging population, which more than offsets the flatness of the use rate.”

Department’s Review

The department performed an extensive review of the historical numbers of OHS within the state and HSA #1 within its review of Standard #c above, and concluded that the volume of OHS from 1997 to 2001 for HSA #1 and the state as a whole have decreased. The department is not certain what the applicants’ are referring to with the statement “the average 1999-2001 experience was relatively flat.” The department does not conclude that the number of OHS performed in HSA #1--or the state--has remained flat, rather, they have decreased. Additionally, although the methodology (or mathematical calculation) concludes that an HSA could support an additional OHS program, it is not a “demonstration of need” for OHS services as stated by the applicants. The applicants’ demonstration of need is evaluated under WAC 246-310-210. Finally, the department previously concluded within this evaluation that with the OHS volumes on the decrease for OHMC, HSA #1, and the state as a whole, approval of this project would simply not be prudent at this time. There was no additional information provided by the applicants to change this conclusion.

Low volumes adversely affect quality and outcomes

“These [OHS] rules state, in part, that if the mathematical calculation produced using the methodology contained in WAC identifies a need, an applicant (that meets all other standards) shall be approved to operate a service. This approval is contingent upon the applicant demonstrating [that it meets the standards a-g]. Unequivocally, the Overlake/Evergreen application has demonstrated conformance with the above standards.”

Department’s Review

WAC 246-310-261 does not state that “if the mathematical calculation produced using the methodology contained in WAC identifies a need, an applicant (that meets all other standards) shall be approved to operate a service” as asserted by the applicants. In fact, WAC 246-310-261 does not even imply that the department must approve an applicant based on the methodology alone. This is demonstrated under WAC 246-310-261(2), which states:

“Open heart surgery is a tertiary service as listed in WAC 246-310-020. To be granted a certificate of need, an open heart surgery program shall meet the standards in this section in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.”

However, under Standards #b, #c, and #d associated with WAC 246-310-261 above, the department evaluated and addressed this concern, and concluded that the application did

¹⁰ The Attachment and the Table are not included in the department's restatements.

not conform to Standards #c and #d. There was no additional information provided by the applicants to change these conclusions.

The applicants also provided extensive background information related to the proposed open heart surgery rules changes currently being considered by the department. The rule changes are still under review and not approved for use in evaluating OHS or PTCA projects. Therefore, the proposed rule changes are irrelevant to this project.

Duplication of existing eastside capacity and services

The applicants did not provide a response to this assertion by Swedish Medical Center.

Department's Review

Swedish Medical Center asserts that creating a separate open-heart facility at EHMC would be a duplication of existing capacity on the eastside. However, while the application states it is a joint program, many aspects are separate--two clinical directors for OHS, two clinical directors for PTCA; two cardiac surgeons and staff--for each facility. Without the extensive documentation from the applicants demonstrating roles and responsibilities for each entity as it relates to the proposed OHS and PTCA programs, the department can neither agree nor disagree with Swedish's assertions. However, it is clear by portions of the application that many areas of OHMC's existing OHS program will be duplicated at EHMC, which appears to be unnecessary given that the applicants are located approximately 8 miles--or 15 minutes--from each other.

Additionally, the University of Washington Medical Center (UWMC) provided comments regarding this application. After reviewing the comments, the department concludes that UWMC is neither in support or opposition to this joint project. The comments are restated below, and have been addressed in the under the standards review portion of this evaluation.

University of Washington Medical Center (restated)

UWMC requests that in its review of these two applications, the Department of Health recognize the special needs of medical education programs. It is critical that the volumes of cardiac bypass graft cases and valve replacement cases in the training programs in our state remain at levels sufficient to provide high quality education experiences for surgeons in training. [source: public comments provided at January 16, 2003, public hearing]

Based on the above evaluation, the joint application submitted by Evergreen Hospital Medical Center and Overlake Hospital Medical Center proposing to establish a regional open heart surgery program and PTCA service within space at Evergreen Hospital Medical Center is not consistent with the standards outlined in WAC 246-310-261.

B. Nonemergent Interventional Cardiology Standard (WAC 246-310-262)

Based on the source information reviewed, the department determines that the applicants have not met the standards in WAC 246-310-262.

All nonemergent percutaneous transluminal coronary angioplasty (PTCA) procedures and all other nonemergent interventional cardiology procedures are tertiary services as defined in WAC 246-310-010 and shall be performed in institutions which have an established on-site open heart surgery program capable of performing emergency open heart surgery.

This criteria states that an applicant must have an on-site OHS program before it provides PTCA services. Given that the joint application from EHMC and OHMC to establish OHS services at EHMC is not consistent with the applicable criteria under WAC 246-310-261, the applicants are precluded from providing OHS services at that site, and, as a result, may not establish PTCA services at the EHMC site. Therefore, this criterion is not met.

Based on the above evaluation, the joint application submitted by Evergreen Hospital Medical Center and Overlake Hospital Medical Center proposing to establish a joint regional open heart surgery program and PTCA service within space at Evergreen Hospital Medical Center is not consistent with the criterion in WAC 246-310-262.

C. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicants have not met the need criteria in WAC 246-310-210.

- (1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

WAC 246-310-210 requires the department to evaluate all Certificate of Need applications on the basis of the population's need for the service. Information provided by EHMC and OHMC to support this criterion is summarized below. [source: Application, pp36-39]

Per WAC 246-310-261, there is a documented need for two additional open-heart surgery providers within HSA #1 by 2006. It is the belief of Overlake and Evergreen that the following factors render the Eastside as the community in greatest need of an additional provider of any area within the HSA.

- The unabated growth and aging of the communities comprising the eastside, and the increasing demand experienced over the past several years for cardiac services.*
- The worsening of traffic congestion and problems during both peak and off-peak travel on major eastside freeway corridors. For acute cardiac episodes, delay in treatment equates to a loss of heart muscle, and increased rates of disability or death, and decreased quality of life. These issues render timely geographic access during a cardiac emergency a paramount concern, especially given the fact that nearly 40% of all open-heart surgeries currently performed on eastside residents at OHMC are performed on an urgent or emergency basis.*
- The increasing preference of eastside residents to stay on the eastside for care.*

The applicants state that there is an increasing demand for cardiac services on the eastside, however, according to the 1999-2001 historical OHS volumes provided at OHMC, while there is an increase in volumes, it is not considered a large increase. For year 1997 to year 2001, OHMC's volumes increased from 351 to 376--only 25 procedures, or 7.1%--not a large increase. Additionally, the number of OHS for the HSA and the state has decreased for the same two years. Therefore, the department does not agree with the applicants that there is "an increase demand experienced over the past several years for cardiac services.

To evaluate the applicants' statements regarding traffic congestion and preference of eastside residents, the department considered information provided by the affected parties. Swedish Medical Center provided extensive documentation related to these statements made by the applicants. [source: public comments provided at January 16, 2003, public hearing] The applicants did not provide rebuttal responses to the statements made by Swedish Medical Center. Below is a summary of the department's review.

Traffic conditions in eastside are improving

The department does not have the extensive personal knowledge to evaluate this issue. It is clear, however, that the applicants are located approximately 8 miles--or 15 minutes--from each other. It is difficult, therefore, to conclude that OHS patients--even emergent patients--could not be transported to OHMC for services. Information provided in the application does not demonstrate that patients residing in the southern and eastern areas of eastside King County (i.e. Renton, Issaquah, Sammamish, & Snoqualmie) would bypass OHMC to receive services at EHMC. Additionally, Swedish Medical Center provided assertions related to the Department of Transportation's (DOT) solutions to the traffic congestions in the eastside of King County and upcoming projects on I-405. This information is substantiated by the DOT

website. The department concludes that traffic in the eastside of King County either is, or will be, improving, which will assist transfer of patients.

Patient preference for location of care

Swedish Medical Center provided a summary of a survey completed by a consulting group. The survey is used to demonstrate by Swedish Medical Center that the majority of patients on the eastside prefer to stay on the eastside for routine care, however, for tertiary services, eastside residents prefer to receive those services in a "Seattle hospital." Swedish Medical Center states that 2001 CHARS data for tertiary services shows that for patients with eastside zip codes, OHMC captures 22% of these patients; EHMC captures 17%, and the remaining 61% receive their tertiary care outside the eastside area--with 31% of those 61% going to a "Seattle area hospital." For OHS services, 33% of the patients receive care at OHMC and 54% receive services at a "Seattle area hospital", the remaining 15% go elsewhere. This information provided by Swedish Medical Center is substantiated by the historical CHARS data. The department concludes that the applicants did not provide compelling information to demonstrate that patient referral patterns will change with the addition of another OHS and PTCA program in east King County.

For an OHS project, the sub-criterion under need requires the applicant to demonstrate that the population to be served has need for the project and other OHS facilities are not or will not be sufficiently available or accessible to meet the need. [emphasis added] The applicants do not provide documentation to support that the patients have a need for this project and other facilities--including OHMC located 8 miles or 15 minutes from EHMC and Northwest Hospital with its current low volumes of OHS--are not available to meet that need. In fact, the historical volumes provided within the CHARS data and used in the methodology demonstrate that the existing providers--including OHMC and Northwest Hospital--have the ability to absorb any increase in volumes in east King County and HSA #1.

As previously stated in the project description portion of this evaluation, open heart surgery and PTCA are tertiary services as defined in WAC 246-310-010, and therefore require sufficient patient volumes to optimize provider effectiveness, quality of service, and improved outcomes of care. For these reasons, open heart surgery is not, and should not be, offered in every hospital within the state. With a tertiary service, it is expected that a patient will be transported some distance to receive quality care from a quality provider. To become a quality OHS and PTCA provider, a hospital must be able to meet the standards set forth in WAC 246-310-261 and -262. The applicants are unable to meet those standards with the establishment of an OHS and PTCA program at EHMC without negatively impacting two established OHS providers--OHMC and Northwest Hospital. Further, the connection among sufficient patient volumes, quality of care, and improved outcomes for tertiary services requires a substantial and compelling demonstration of need for the services by the patient and the community. Additionally, in order to maintain themselves as a quality provider with improved outcomes for OHS services, both OHMC and EHMC would have to continue to perform at least 250 OHS per year, or 500 total OHS per year. While the applicants argue that the OHS program will be a joint program, if both hospitals are anticipating on maintaining their OHS and PTCA capability, both hospitals would have to provide the minimum volume of 250 procedures each to ensure that all staff, not just the cardiologists, are maintaining the skills necessary to achieve the quality outcomes. Given the decrease of OHS in HSA #1 and Washington State as a whole--a common trend across the nation--the department is not confident that EHMC would perform 250 OHS by the end of the third year of operation or that either OHMC or EHMC would maintain the required 250 volume in subsequent years.

Concerns raised in opposition to this project related to the need criteria under WAC 246-310-261 were provided by Everett Cardiac Surgical Group and Providence Everett Medical Center. The department has summarized the concerns below.

Everett Cardiac Surgical Group (summarized)

The application should be denied as there is not a need in the community or a clinical benefit. [source: public comments provided at January 16, 2003, public hearing]

Providence Everett Medical Center (summarized)

Opposition is based on the following grounds:

- The application fails to substantiate community need;
- The Application does not have a demonstrable clinical benefit.

[source: public comments provided at January 16, 2003, public hearing]

The applicants did not provide rebuttal responses to the statements made by above by Everett Cardiac Surgical Group and Providence Everett Medical Center. In any case, after reviewing the application and substantial documentation received, the department concurs that the applicants failed to demonstrate need for an additional OHS and PTCA program on the eastside of King County. In summary, the department concludes that the applicants did not demonstrate that the population served or to be served has need for the OHS and PTCA services and existing facilities--including OHMC-- are not or will not be sufficiently available or accessible to meet that need as required in WAC 246-310-210. This sub criterion is not met.

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

All residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently have access to services at both EHMC and OHMC. The approval of OHS and PTCA services at EHMC is not expected to change this access. Current admission policies provided by the applicants demonstrate that patients are admitted to both facilities for treatment without regard to age, race, color, religion, sex, national origin, handicap, or sexual preference and will be treated with respect and dignity. [source: Application, Appendices 6 and 7]

For charity care reporting purposes, the OHPDS, divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. EHMC and OHMC are two of 17 hospitals located within the King County Region. According to 1999–2001¹¹ charity care data obtained from OHPDS, EHMC has historically provided an average of charity care greater than the King County regional average. EHMC's most recent three years (1999-2001) percentages of charity care for gross and adjusted revenues are 1.01% and 1.6%, respectively. The 1999-2001 average for the King County Region is .84% for gross revenue and 1.40% for adjusted revenue.¹² OHMC, on the other hand, has historically provided an average of charity care less than the King County regional average. OHMC's percentages of charity care for gross and adjusted revenues are .99% and 1.52%,

¹¹ Year 2002 charity care data is not available as of the writing of this evaluation.

¹² Harborview Medical Center is subsidized by the state legislature to provide charity care services. Charity care percentages for Harborview make up almost 50% of the total percentages provided in the King County Region. Therefore, for comparison purposes, the department excluded Harborview Medical Center's percentages.

respectively. [source: OHPDS 1999-2001 charity care summaries] The applicants indicate that the proposed OHS program would provide charity care, however, given that the ECCA entity has not yet been established, and therefore, has no established or draft admission policies or charitable policies, if this project is approved, the applicants would have to agree to a condition related to the amount of charity care to be provided. With a charity care condition the department concludes that all residents of the service area would have adequate access to the health services at EHMC, and this sub-criterion would be met.

D. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicants have not met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

To analyze short- and long-term financial feasibility of hospital projects and to assess the financial impact of a project on overall facility operations, the department uses financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically utilized are **1)** long-term debt to equity ratio; **2)** current assets to current liabilities ratio; **3)** assets financed by liabilities ratio; **4)** total operating expense to total operating revenue ratio; and **5)** debt service coverage ratio. If a project's ratios are within the expected value range, the project can be expected to be financially feasible.

For this joint project, the only ratios that apply are the long-term debt to equity ratio and the total operating expense to total operating revenue ratio. The remaining ratios are more appropriate to evaluate when an applicant intends to finance a project from an outside source. The \$1,800,000 funding for this project will come solely from EHMC's board designated assets. [source: Application, p99-100, and OHPDS analysis, p2] Table IX below shows the two applicable ratios for this project, in the first three years of operation for EHMC as a whole, with the OHS and PTCA services, and the Office of Hospital and Patient Data Systems (OHPDS) year 2001 financial ratio guidelines for hospital operations. [source: OHPDS analysis, pp2-3]

**Table IX
Evergreen Hospital Medical Center's Current and Projected Financial Ratios**

Financial Ratio	OHPDS Guideline		EHMC Current Year 2001	Year 1 2005	Year 2 2006	Year 3 2007
Long Term Debt to Equity	0.529	* Below	0.922	0.868	0.809	0.752
Total Operating Expense to Total Operating Revenue	0.976	* Below	0.525	0.507	0.490	0.474

* = a project is considered more feasible if the ratios are above or below the value/guideline as indicated

After reviewing the financial information provided by the applicants, staff from OHPDS stated the following:

"[the] Long-Term Debt to Equity ratio at the end of 2001 is .922, which is above the 2001 state average of .529 as calculated by [this office]. Evergreen has taken on debt recently and is finishing up a major remodeling project. The ratios are appropriate for a project like this. Evergreen's financial health is slightly below the average as compared to the community hospitals whose data is collected by this office. This should not affect this project, however. The hospital has performed adequately in the past and this ratio should improve in the near term. [source: OHPDS analysis, pp2-3]

Additionally, as previously stated in this evaluation, EHMC projects to provide 150 OHS and 125 PTCA procedures in year one (2005), 210 and 150 in year two, and 260 OHS and 175 PTCA procedures by the end of the third year of operation (2007). Based on those projections, Table X shows the revenue, expenses, and net income projected by the applicants in the first three years of operation for the joint OHS and PTCA program. [source: Application, Exhibit 10 and OHPDS analysis, p 4]

Table X
Evergreen Hospital Medical Center's
Projected Revenue and Expenses for OHS and PTCA Program

	Year 1 -- 2005	Year 2 -- 2006	Year 3 -- 2007
Projected # of OHS patients	150	210	260
Project # of PTCA patients	125	150	175
Projected # of patient days (both)	900	1,260	1,560
Net Patient Revenue	\$ 5,323,773	\$ 6,967,132	\$ 8,184,220
Operating Expense	\$ 6,508,506	\$ 7,227,956	\$ 7,866,406
Annual Net Income/(Loss)	(\$ 1,184,733)	(\$ 260,824)	\$ 317,814

Operating Revenue per Pt. Day	\$ 5,915	\$ 5,529	\$ 5,246
Operating Expense per Pt Day	\$ 7,232	\$ 5,736	\$ 5,043
Net Income/(Loss) per Pt. Day	(\$ 1,316)	(\$ 207)	\$ 204

Numbers may not add due to rounding

As noted in Table X above, the applicants project a net loss for the OHS and PTCA program in the first two years of operation, and anticipate a net profit in year three. The pro forma expenses shown above include allocated costs. These costs represent the OHS and PTCA program's fair share of hospital non-revenue producing expenses (such as administration). With these costs included, operating revenues are expected to exceed operating expenses by the end of the third year of operation.

After reviewing the financial information provided by the applicants, staff from OHPDS stated the following:

"When I calculated the average charges per open heart and per PTCA patient using the entire cost of the program provided by the applicants, the result is comparable to surgery charges at other hospitals as reported through the CHARS in 2002 first half." [source: OHPDS analysis, p3]

The applicants anticipate that the OHS and PTCA program located at EHMC will begin to cover costs in its second year of operation. However, in the need section of this evaluation, the department voiced concerns regarding EHMC's ability to achieve the minimum volume of 250 procedures and both facility's ability to maintain those volumes given the decline in OHS procedures within the HSA, Washington State, and across the nation. However, based solely mathematical calculations within the methodology and referral documentation provided by EHMC, the department concludes that the projections above are reasonable and the hospital would be able to meet its short and long term financial obligations, and its capital and operating costs of the project would be met. This sub-criterion is met.

- (2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

OHPDS also compared EHMC's costs and charges to the year 2002 (six months) statewide average and determined that they are reasonable. [source: OHPDS analysis, p3]

As previously stated, the capital expenditure for the joint OHS and PTCA program at EHMC is projected to be \$1,800,000, and the majority of the expenses (91%) is related to purchasing moveable equipment for the new program. [source: Application, p99 and October 30, 2002, supplemental information, p7]

In the need section of this evaluation, the department concluded that the applicants failed to demonstrate that the population has a need for this project and existing providers are not available to meet the future need for OHS and PTCA services in the community. Given that the project is not necessary, the department also concludes that the costs of this project will probably result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

(3) The project can be appropriately financed.

The \$1,800,000 capital expenditure for this project will be funded from board designated assets (or hospital reserves) from funds generated from operations at EHMC. OHMC will not be providing any funding for this project. [source: Application, p99 and October 30, 2002, supplemental information, p7]

After reviewing EHMC's December 31, 2001, audited financial report, staff from OHPDS provided the following evaluation:

"Evergreen indicates it will use reserves (board designated assets) to finance this project. \$1,800,000 is .60% of total assets and approximately 2.69% of reserves when compared to the 2001 fiscal year end balance sheet. The use of reserves is very inexpensive. Reserves are accumulated mainly from prior year profits. The only cost would be that the money would not be available for other uses. This project will not impact reserves, total assets, total liability, or the general health of the hospital in a significant way. The financing method used is appropriate" [source: OHPDS analysis, p2 & 4]

As noted by OHPDS, the capital costs for this project will not have an effect on EHMC's reserves, nor will it adversely affect the hospital's total assets, total liability, or general financial health. Therefore, the department concludes that the proposed financing is appropriate, and this sub-criterion is met.

E. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicants have not met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

As stated in the project description portion of this evaluation, before the services are established, OHMC and EHMC will establish, and be sole owners of, a new entity--Eastside Cardiac Care Alliance (ECCA). To establish OHS and PTCA services at EHMC, ECCA will enter into agreements with both hospitals, and ultimately be responsible for day-to-day operations of a single OHS and PTCA service operating at both hospitals. Joint management of the OHS and PTCA services will include: medical staffing, policies and

procedures, quality assurance, professional education, and community outreach. [source: Application, pp7-8]

The applicants proposed 24 additional FTEs will be added in the first year of operation (year 2005) and an additional 7.5 will be added by the end of the third year of operation (2007), for an FTE total of 31.55, not including the cardiologists to be associated with the program. [source: Application, p106]

In response to this criterion, the applicants provided a breakdown of the proposed FTES shown in Table XI below.

Table XI
Evergreen Hospital Medical Center's
Projected FTEs for OHS and PTCA Program

	Year 1 -- 2005	Year 2 -- 2006	Year 3 -- 2007
Nursing	16.95	21.60	24.00
Surgery	3.50	3.50	3.50
Pharmacy	1.25	1.50	1.75
Radiology	1.50	1.50	1.50
Other	0.80	0.80	0.80
Total	24.00	28.90	31.55

The applicants also provided the following statements related to staffing of the proposed OHS and PTCA program at EHMC.

"...the development of a second eastside open heart site at Evergreen, undertaken jointly, enables the new site to benefit from the experience and expertise of Overlake. The existing team of cardiac surgeons and perfusionists that work at Overlake will also perform the surgeries at Evergreen. In addition to the existing cardiac surgeons, [ECCA] will also jointly recruit additional surgeons. In terms of direct clinical staff, Evergreen will need to recruit 24 additional FTEs to commence the service. ...because the program will not start until January 2005, it is envisioned that a formal preceptorship program will be established that will allow for the training of existing staff interested in cardiac surgery. Additionally, in developing a recruitment and training program for the second site, Human Resources and Clinical Education staff from both hospitals will work closely together, and will build off of existing proven strategies at both hospitals, including existing internships and residency programs. Finally, the consolidation of the management between the two open-heart and elective intervention programs minimizes the need for additional administrative and management staff."

[source: Application, p161]

Concerns raised in opposition to this project related to the criterion under WAC 246-310-230 centered on staffing of the proposed program. The concerns, provided by Swedish Medical Center, are summarized below.

Staff shortage would prolong adequate staffing of programs

Swedish Medical Center asserts that with the current nationwide healthcare workforce shortage--vacancy rates for nurses is 11% in year 2001--the applicants may have difficulty recruiting the 70%-76% nursing staff anticipated to be needed for this project. Further, staffing shortages could negatively impact quality of a program and budget cuts are expected to worsen the existing workforce shortage. Swedish Medical Center asserts that

the nursing shortage, combined with the high rate of turnover and lack of government funding and support, will make it difficult to recruit and maintain high quality staff for existing programs, let alone any new programs.

The applicants did not provide a response to the concerns provided by Swedish Medical Center.

Department's Review

The department recognizes that Washington State, as well as the rest of the nation, is in the midst of a healthcare workforce shortage, which undoubtedly results in challenges for recruitment and retention of staff for all healthcare providers, including hospitals. For this criterion, the department must evaluate whether an applicant has provided sufficient documentation to demonstrate sufficient planning and recruitment for proposed staff. In the case of this project, the applicants provided documentation that it has planned for sufficient staffing and recruitment efforts for the program. Additionally, the applicants have identified some key positions for the proposed OHS and PTCA services at EHMC. Those positions include: the medical director, cardiac physicians, and the surgical services manager and cath lab manager to be located at EHMC.

Standard #d within this evaluation relates to the cardiac surgeon staffing of the program. Under this standard, an applicant must demonstrate that two board-certified cardiac surgeons are associated with the program, and one of the surgeons must be available for emergency surgery twenty-four hours a day. The standard also requires that the practice of these surgeons shall be concentrated in a single institution and arranged so that each surgeon performs a minimum of 125 open heart surgery procedures per year at that institution, for a total of 250 OHS per year. Within this evaluation, the department concluded that without at least a draft agreement between ECCA and the two hospitals, it was unable to conclude that the intent of this standard is met. There is no additional information provided in the application to change this conclusion related to standard #d, therefore, the department must also conclude that this sub-criterion is not met.

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

The applicants state that the proposed OHS services will serve patients 15 years of age and older, and EHMC will continue to use its existing protocol for transporting patients to the hospitals and physicians in HSA #1. As stated in the project description portion of this evaluation, patients 14 years and younger will primarily be referred to Children's Hospital and Regional Medical Center in Seattle. The applicants anticipate no change in these referral patterns with the establishment of the proposed OHS and PTCA services at EHMC. [source: October 31, 2002, supplemental responses, p5] The department concludes that this sub-criterion is met.

- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

The applicants both provide Medicare and Medicaid acute care services to the residents of their respective service areas. Within the most recent four years, the Department of Health's Office of Health Care Survey (OHCS), which surveys hospitals within Washington

State, has completed three compliance surveys for the EHMC.¹³ The surveys revealed minor non-compliance issues typical of a hospital, and EHMC submitted a plan of corrections for the non-compliance issues within the allowable response time. EHMC also operates a Medicare certified home health agency that serves King and Snohomish counties. Within the most recent four years, OHCS also completed two compliance surveys for its home health agency.¹⁴ The agency's surveys also revealed minor non-compliance issues typical of a home health agency, and, again, EHMC submitted a plan of corrections for the non-compliance issues within the allowable response time. [source: Office of Health Care Survey compliance survey data for hospitals and home health agencies]

For the co-applicant, OHMC, within the most recent three years, OHCS completed three compliance surveys for the hospital.¹⁵ The surveys revealed minor non-compliance issues typical of a hospital, and OHMC submitted a plan of corrections for the non-compliance issues within the allowable response time. Additionally, OHMC is one-third owner of a freestanding ASC located on the hospital campus. Within the most recent three years, OHCS also completed one compliance survey for the ASC.¹⁶ The ASC's survey also revealed minor non-compliance issues typical of an ASC, and, again, OHMC submitted a plan of corrections for the non-compliance issues within the allowable response time. [source: Office of Health Care Survey compliance survey data for hospitals and ASC]

The applicants identified the cardiac physicians associated with the existing OHS and PTCA program at OHMC. A review of the compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions for all. [source: Medical Quality Assurance Commission physician compliance history] Further, the applicants identified Joseph Austin, MD as the proposed medical director for the new services. Based on EHMC's hospital and home health agency compliance history and OHMC's hospital and ASC compliance history, and the compliance history of the physicians--including the proposed medical director--the department concludes that there is reasonable assurance that both hospitals would continue to operate in conformance with state and federal regulations with the addition of OHS and PTCA services. This sub-criterion is met.

As a side note, however, the department is particularly concerned that EHMC has performed 234 emergent coronary interventions, given that EHMC does not have an approved OHS program. [source: Application, p38] WAC 246-310-262 states (in summary) that PTCA procedures shall be performed in institutions which have an established on-site open heart surgery program capable of performing emergency open heart surgery. 234 unauthorized procedures averages to one procedure every 1.5 days. This number appears to be especially high for emergent procedures, especially since it is more than the applicants propose to be provided in the first three years of operation at EHMC. Additional, it appears to be excessive given that OHMC's existing OHS and PTCA program is located within 8 miles from EHMC. The department will monitor the volumes at EHMC.

- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

In response to this criterion, the applicants state the following:

¹³ Surveys conducted 1999, 2001, and 2002.

¹⁴ Surveys conducted in 2000 and 2002.

¹⁵ Surveys conducted in 2000, 2001, and 2002.

¹⁶ Survey conducted in 2000.

“Improved and enhanced geographic access and continuity of care, along with the desire to minimize delays in treatment, are the fundamental drivers of the two hospitals coming together to develop a second site for open heart surgery on the eastside. Under the current delivery system and as detailed in the need section of this application, all of the patients presenting at Evergreen that need emergent surgery are transferred to another hospital--either to Overlake or downtown. This transfer problem is particularly concerning for those patients who require an emergency surgical intervention following a myocardial infarction. After initial presentation (which can be delayed for up to several hours) travel time for emergency transport, which includes waiting for transportation, preparing the patient for transport, and then preparation time at the receiving hospital delays the actual intervention. In addition to these clinical delays, the current system can also result in fragmented care. All of Evergreen’s cardiologists are also on the medical staff of Overlake. However, there is a shortage of cardiologists on the eastside, so that if the on-call cardiologist follows an emergent patient from Evergreen to Overlake, that cardiologist is no longer immediately available to respond to the next emergency at Evergreen, which can potentially cause problems with the emergency medical response system. The improved geographic access resulting from approval of this project will enhance continuity of care for eastside residents.”

[source: Application, p163]

The department understands the applicants’ arguments regarding the transport of patients and disruptions to the family and patient. However, the department does not concur regarding continuity of care. Continuity of care is not limited by a facility. Depending on the patient’s needs, continuity of care may include transport of the patient to the most appropriate provider. For tertiary services, continuity of care means a hospital’s ability and willingness to triage and transport as necessary to the most appropriate tertiary provider. For emergent OHS or PTCA patients, this will mean that the patient will be transported to a physician or physician group who has not previously seen the patient. In this case, continuity of care also means that the referring hospital provides specific patient information and documentation to the receiving facility. Additionally, continuity of care also includes the communication and sharing of patient information between physicians in different facilities or physicians within the same facility. Further, with a tertiary program where there is a direct connection among sufficient patient volumes and provider effectiveness, quality of service, and improved outcomes of care, the department concludes that the establishment of a quality provider in this health care service is far more critical than patient, family, or physician convenience.

Additionally, the department concluded that that OHS volumes are declining in HSA #1 and Washington State--which is a national trend--and was not confident that EHMC would reach 250 OHS by the end of the third year of operation or that both EHMC and OHMC would maintain the required 250 volume in the subsequent years. The department also concluded that the establishment of an OHS and PTCA program at EHMC would reduce an existing, established provider below the 250 standard--OHMC; and further reduce an existing provider below the 250 standard--Northwest Hospital. If all of the department’s concerns were realized, the result would be three OHS and PTCA programs operating below the 250 standard and potentially unable to maintain quality programs. The final result would be a fragmentation of existing services in King County and HSA #1. Therefore, the department concludes that approval of this project has the potential of fragmentation of OHS and PTCA services within HSA #1, and this sub-criterion is not met.

- (5) *There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.*
This sub-criterion is addressed in sub-section (3) above.

F. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicants have not met the cost containment criteria in WAC 246-310-240.

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

The applicants state that once the decision was made to work together to improve geographic access and availability, the only remaining alternative to consider was the organizational structure of the partnership. Therefore, before submitting this application, the applicants considered and rejected the two options below:

- Evergreen operating its own program and contracting with Overlake for various services; or
- Overlake leasing space at Evergreen and operating the service.

The applicants state that from a quality and cost-efficiency perspective, one single program operating at two sites--this application--was deemed the superior alternative the to two options above. [source: Application, p166] Within this application, the applicants do not provide any discussion of the two options above and an explanation of why either of the options were rejected. In any event, under current CN rules, regardless of which of the two options were selected, prior CN review and approval is required.

One of the options not considered by the applicants is status quo. Given the conclusions reached by the department under the OHS and PTCA standards (WAC 246-310-261 and -262, respectively) , the criterion of need (WAC 246-310-210), financial feasibility (WAC 246-310-220), and structure and process of care (WAC 246-310-230), the department concludes that status quo is the best available option. As a result, the department does not conclude that approval of this project is the best available alternative for the residents of the service area.

On the basis of these conclusions, the department concludes that approval of this project is not the best available alternate for the service area, and this sub-criterion is not met.